Artifen Tablet

Artifen (Diclofenac Sodium)

DESCRIPTION:
Artifen is a nonsteroidal anti-inflammatory drug (NSAID) that is used to relieve pain and inflammation due to certain medical conditions.

CLINICAL PHARMACOLOGY:
Artifen is rapidly absorbed into the plasma with peak levels occurring at around two hours. It is extensively bound to proteins. The elimination half life is in order of 1.2 to 1.8 hours. Diclofenac sodium is metabolized in the liver by glucuronidation and to a lesser extent by presystemic oxidation and N-dealkylation, with renal excretion of the unmetabolized drug and its glucuronide conjugate as the major routes of elimination. Diclofenac sodium is extensively bound to plasma proteins, predominantly to albumin. The drug is removed from plasma by filtration at the glomerulus.

INDICATIONS:
Artifen is indicated:
- For the relief of symptoms of osteoarthritis and rheumatoid arthritis.
- For the relief of symptoms of ankylosing spondylitis.
- For the relief of signs and symptoms of gout.
- For the relief of signs and symptoms of dysmenorrhea.
- For the relief of signs and symptoms of chronic juvenile arthritis.
- For the relief of signs and symptoms of other inflammatory disorders including osteoarthritis, ankylosing spondylitis, and juvenile rheumatoid arthritis.
- For the relief of signs and symptoms of acute gout.

SIDE EFFECTS:
Artifen may cause gastrointestinal disturbances such as nausea, vomiting, diarrhea, or constipation. Other side effects may include headache, tinnitus, dizziness, skin rashes, fluid retention, and peripheral edema.

OVERDOSAGE:
Symptoms following acute NSAID overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, epigastric pain, and dehydration. Severe, rarely fatal, anaphylactic-like reactions to aspirin and other NSAIDs have been reported in such aspirin-sensitive patients. Severe, rarely fatal, anaphylactic-like reactions to Artifen have also been reported. Patients with aspirin-sensitive asthma may have aspirin-sensitive asthma.

GASTROINTESTINAL RISK:
NSAIDs, including diclofenac, the CBC and a chemistry profile (including transaminase levels) should be monitored in patients treated with Artifen. Because serious GI tract ulcerations and bleeding can occur without warning symptoms, physicians should monitor patients in risk categories and should inform patients of the need for immediate medical care if symptoms of GI distress occur. Because serious ulceration and bleeding can occur, physicians should monitor patients in risk categories and should inform patients of the need for immediate medical care if symptoms of GI distress occur.

CARDIOVASCULAR RISK:
NSAIDs cause an increased risk of serious gastrointestinal adverse events including inflammation, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur without warning symptoms. NSAIDs cause an increased risk of serious cardiovascular adverse events including myocardial infarction or stroke, which can be fatal. These events can occur without warning symptoms. NSAIDs cause an increased risk of serious renal adverse events, including nephrotic syndrome.

INFORMATION FOR PATIENTS:
Patients should be counseled that NSAIDs, including Artifen, can cause serious adverse reactions including gastrointestinal bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur without warning symptoms. Patients should be counseled about the risk of严重 gastrointestinal bleeding associated with the use of NSAIDs, particularly in patients with a history of ulcer disease or concomitant use of warfarin, aspirin, or other NSAIDs. Patients should be counseled about the risk of serious cardiovascular adverse reactions, including myocardial infarction and stroke, particularly in patients with a history of coronary artery disease or concomitant use of other risk factors such as diabetes mellitus, hypertension, age 70 years or older, or concomitant use of aspirin or other NSAIDs. Patients should be counseled about the risk of serious renal adverse reactions, including nephrotic syndrome, which can occur without warning symptoms. Patients should be counseled about the risk of serious hepatic adverse reactions, including hepatic necrosis, which can occur without warning symptoms. Patients should be counseled about the risk of serious skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, which can occur without warning symptoms. Patients should be counseled about the risk of serious allergic reactions, including anaphylaxis, which can occur without warning symptoms. Patients should be counseled about the risk of serious hypersensitivity, including anaphylaxis, which can occur without warning symptoms. Patients should be counseled about the risk of serious cardiovascular adverse reactions, including myocardial infarction and stroke, which can occur without warning symptoms. Patients should be counseled about the risk of serious gastrointestinal adverse reactions, including perforation, which can occur without warning symptoms. 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